IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

CONNIE HUNTER	)	Case No.: 4:19-cv-1634
Plaintiff,	)	**COMPLAINT AND JURY DEMAND**
vs.	)	
JOHNSON & JOHNSON and ETHICON, INC.,	)	
Defendants	)	

Plaintiff Connie Hunter by and through her attorneys, Dunken Law Group, PLLC and Holland Law Firm, PC, bring this Complaint and Jury Demand against Ethicon, Inc. and Johnson & Johnson and allege the following based upon personal knowledge, information and belief and investigation of counsel.

NATURE OF ACTION

1. This action seeks to recover damages for injuries sustained by Plaintiff Connie Hunter as the direct and proximate result of the wrongful conduct of Ethicon, Inc. and Johnson & Johnson in connection with the designing, developing, manufacturing, distributing, labeling, advertising, marketing, promoting and selling of transvaginal mesh.

PARTIES, JURISDITION AND VENUE

2. Plaintiff Connie Hunter was at all times alleged herein, a citizen and resident of St. Louis, St. Louis County, MO. Plaintiff has suffered damages as a result of Ethicon, Inc. and Johnson & Johnson's illegal and wrongful conduct alleged herein.

3. Defendant, Johnson & Johnson is a corporation, and according to its website, the world's largest and most diverse medical device and diagnostics company, with its worldwide

headquarters located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. Johnson & Johnson organizes its subsidiary businesses into individual Business Units to coordinate the development, manufacture, testing, marketing promotion, training, distribution and sale of its pelvic floor repair Gynecare TVT Exact® Continence System. For diversity purposes, Johnson & Johnson is a citizen of New Jersey.

4. Defendant, Ethicon, Inc., is a wholly owned subsidiary of Defendant Johnson & Johnson with its principal place of business located in Somerville, New Jersey. For diversity purposes, Ethicon, Inc. is a citizen of New Jersey.

5. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(a), in that there is complete diversity among Plaintiff and Ethicon, Inc. and Johnson & Johnson and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

6. Venue in this action is proper pursuant to 28 U.S.C. § 1391(a) and (c), as a substantial number of the events, actions, and omissions giving rise to Plaintiff's claims occurred in this district. At all times material hereto, Ethicon, Inc. and Johnson & Johnson were for profit corporations authorized to and doing substantial business in the state of Missouri.

7. At all times alleged herein, Johnson and Johnson, Inc. and Ethicon, Inc. included and includes any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint ventures, and organizational units of any kind, their predecessors, successors, and assigns and their officers, directors, employees, agents, representatives, and any and all other persons acting on their behalf.

8. Defendant Ethicon, Inc., develops technology to diagnose and treat conditions related to the pelvic health of women.

9. At all times relevant herein, Ethicon, Inc., was engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, packaging, labeling, and selling such devices, including the Gynecare TVT Exact® Continence System. Ethicon, Inc. manufactures, markets, advertises, promotes, and sells the Gynecare TVT Exact® Continence System worldwide.

10. At all times relevant herein, Ethicon, Inc., designed and manufactured the Gynecare TVT Exact® Continence System, including that which was implanted in Plaintiff Connie Hunter, which gives rise to the Plaintiff's claims asserted herein.

11. At all times relevant herein, Ethicon, Inc., packaged the Gynecare TVT Exact® Continence System, including that which was implanted in Plaintiff Connie Hunter, which gives rise to the Plaintiff's claims asserted herein.

12. At all times relevant herein, Ethicon, Inc., labeled the Gynecare TVT Exact® Continence System, including that which was implanted in Plaintiff Connie Hunter, which gives rise to the Plaintiff's claims asserted herein.

13. At all times relevant herein, Ethicon, Inc. sold the Gynecare TVT Exact® Continence System throughout the United States, including the state of Missouri.

14. This is an action for damages in excess of $75,000, exclusive of interest, costs and attorney's fees. Subject matter jurisdiction is proper pursuant to 28 U.S.C. § 1332.

15. Ethicon, Inc. and Johnson & Johnson have transacted business within the state of Missouri and this Court has personal jurisdiction over Ethicon, Inc. and Johnson & Johnson under the Missouri Long Arm Statute, Mo. Rev. Stat. § 506.500.

16. Ethicon, Inc. and Johnson & Johnson have committed a tortious injury in the state of Missouri caused by their acts and/or omissions inside and outside the state of Missouri they are

subject to jurisdiction in this Court under the Missouri Long Arm Statute, Mo. Rev. Stat. § 506.500., by virtue of their regular conduct and solicitation of business in this state, their continued derivation of substantial revenue from goods used or consumed in Missouri, and based on their otherwise persistent course of conduct in Missouri.

17. Ethicon, Inc. and Johnson & Johnson have purposefully and systematically committed acts and consummated transactions in the state of Missouri from which they have derived and continue to derive substantial revenues, and they have otherwise committed purposeful actions in the state of Missouri which should have led them to reasonably anticipate being hauled into court in Missouri. Jurisdiction is proper in this Court with respect to Ethicon, Inc. and Johnson & Johnson.

18. As set forth above, a substantial part of the events and omissions giving rise to Plaintiff's causes of action occurred in the Eastern District of Missouri and venue is proper in the Eastern District of Missouri under 28 U.S.C. § 1391 (a) and (c).

FACTUAL BACKGROUND

19. Plaintiff Connie Hunter was implanted with a Gynecare TVT Exact® Continence System, Lot No. 3764318 during surgery performed by Faressa Khan, MD at Missouri Baptist Medical Center, 3015 North Ballas Rd., St. Louis, MO 63131 on or about July 22, 2014.

20. The Gynecare TVT Exact® Continence System was implanted in Plaintiff Connie Hunter to treat her for stress urinary incontinence and other symptoms, the use for which the Gynecare TVT Exact® Continence System was designed, marketed and sold.

21. Defendant Ethicon, Inc. and Johnson & Johnson at all times material hereto, manufactured the Gynecare TVT Exact® Continence System.

22. Defendant Ethicon, Inc. at all times material hereto, was engaged in the business of placing medical devices in the stream of commerce by designing, manufacturing, marketing, packaging, labeling, and selling such devices, including the Gynecare TVT Exact® Continence System which was implanted in Plaintiff Connie Hunter which gives rise to the Plaintiff's claims asserted herein.

23. Defendant Ethicon, Inc. at all times material hereto designed the Gynecare TVT Exact® Continence System, including that which was implanted in Plaintiff Connie Hunter, which gives rise to the Plaintiff's' claims asserted herein.

24. Defendant Ethicon, Inc. at all times material hereto marketed the Gynecare TVT Exact® Continence System, including that which was implanted in Plaintiff Connie Hunter, which gives rise to the Plaintiff's' claims asserted herein.

25. Defendant Ethicon, Inc. at all times material hereto marketed the Gynecare TVT Exact® Continence System through television, print and internet advertising and by sending sales representatives throughout the United States and to the state of Missouri to promote the sale of the Gynecare TVT Exact® Continence System, including that which was implanted in Plaintiff Connie Hunter.

26. Defendant Ethicon, Inc. at all times material hereto packaged the Gynecare TVT Exact® Continence System, including that which was implanted in Plaintiff Connie Hunter.

27. Defendant Ethicon, Inc. at all times material hereto labeled the Gynecare TVT Exact® Continence System by placing its name on the outside of the Gynecare TVT Exact® Continence System's packaging.

28. Defendant Ethicon, Inc. at all times material hereto, labeled the Gynecare TVT Exact® Continence System by placing its name on the paper inside the Gynecare TVT Exact® Continence System's packaging.

29. Defendant Ethicon, Inc. at all times material hereto, sold the Gynecare TVT Exact® Continence System throughout the United States, including the state of Missouri.

30. Due to the Gynecare TVT Exact® Continence System's defects, Defendant Ethicon, Inc's negligence and Defendant's breach of express and implied warranties as described herein, Plaintiff Connie Hunter has suffered severe and permanent bodily injuries and significant mental and physical pain and suffering, and economic losses.

31. Section of the Medical Device Amendment to the Food, Drug and Cosmetics Act ("Section 510(k)") allows the marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 29, 1976.

32. A predicate device is one that the Food and Drug Administration ("FDA") has placed into one of three classification categories and "cleared" for marketing. These regulatory classification categories include Class I, Class II, and Class III medical devices.

33. Under Section 510(k), a manufacturer must provide a premarket notification that allows the FDA to determine whether the device is substantially equivalent to a predicate device.

34. Under Section 510(k), no formal review for safety or efficacy is required.

35. The Gynecare TVT Exact® Continence System manufactured by Ethicon, Inc. is considered a Class II medical device under the FDA's medical device regulatory classification system.

36. In 2010 Ethicon, Inc. and Johnson & Johnson sought and obtained the FDA's approval to market the Gynecare TVT Exact® Continence System under Section 510(k).

37. Ethicon, Inc. was, or should have been, aware of the dangers inherent in Gynecare TVT Exact® Continence System generally, notwithstanding the fact that these Gynecare TVT Exact® Continence System were "cleared" for sale by the FDA.

38. As a result of having the Gynecare TVT Exact® Continence System implanted in her, Plaintiff Connie Hunter has experienced significant mental and physical pain, disability, suffering, has sustained permanent injury, and permanent and substantial physical deformity, has suffered financial or economic loss, including, but not limited to obligations for medical services and expenses, lost income, has endured impaired physical relations during intimacy, and other damages.

39. On July 13, 2011, the FDA issued a Safety Communication wherein the FDA stated that "serious complications associated with surgical mesh for transvaginal repair of POP are not rare."

40. The FDA Safety Communication also stated, "Mesh contraction (shrinkage) is a previously unidentified risk of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA . . . Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain."

41. The FDA Safety Communication further indicated that the benefits of using transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks.

42. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk."

43. Contemporaneously with the Safety Communication, the FDA released a publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the "White Paper"). In the White Paper, the FDA noted that the published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh."

44. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk." (Emphasis in original).

45. The FDA White Paper further stated that "these products are associated with serious adverse events . . . Compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair."

46. In its White Paper, the FDA advised doctors to, inter alia, "[r]ecognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications."

47. The FDA concluded its White Paper by stating that it "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

48. Ethicon, Inc. and Johnson & Johnson knew or should have known about the risks and complications identified in the FDA Safety Communication.

49. Ethicon, Inc. and Johnson & Johnson knew or should have known that their Gynecare TVT Exact® Continence System unreasonably exposed patients to the risk of serious

harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

50. The scientific evidence shows that the material from which Ethicon, Inc. and Johnson & Johnson's Gynecare TVT Exact® Continence System are made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Gynecare TVT Exact® Continence System, including Plaintiff Connie Hunter.

51. This negative response promotes inflammation of the pelvic tissue and contributes to the formation of severe adverse reactions to the mesh, such as those experienced by Plaintiff Connie Hunter.

52. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction." Ethicon, Inc. and Johnson & Johnson's Gynecare TVT Exact® Continence System was unreasonably susceptible to degradation and fragmentation inside the body.

53. Ethicon, Inc. and Johnson & Johnson's Gynecare TVT Exact® Continence System was unreasonably susceptible to shrinkage and contraction inside the body.

54. Ethicon, Inc. and Johnson & Johnson's Gynecare TVT Exact® Continence System was unreasonably susceptible to "creep" or the gradual elongation and deformation when subject to prolonged tension inside the body.

55. Ethicon, Inc. and Johnson & Johnson's Gynecare TVT Exact® Continence System has been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices, implanted by safe and effective, minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of pelvic organ prolapse and stress urinary incontinence, and other competing products.

56. Ethicon, Inc. and Johnson & Johnson intentionally, recklessly and/or negligently concealed, suppressed, omitted and misrepresented the risks, dangers, defects, and disadvantages of their Gynecare TVT Exact® Continence System, and advertised, promoted, marketed, sold and distributed the Gynecare TVT Exact® Continence System as safe medical devices when Ethicon, Inc. and Johnson & Johnson knew or should have known that the Gynecare TVT Exact® Continence System was not safe for their intended purposes, and that the Gynecare TVT Exact® Continence Systems would cause, and did cause, serious medical problems, and in some patients, including Plaintiff Connie Hunter's injuries.

57. For example, Ethicon, Inc. and Johnson & Johnson described in its Patient Brochures, Instructions for Use, and other marketing materials, that the known complications for its Gynecare TVT Exact® Continence System was consistent with any surgical procedure of an implantable medical device and described such occurrences as "rare" and "small" when in fact Ethicon, Inc. and Johnson & Johnson knew or should have known that the complications were not "rare nor small" but common, permanent, and debilitating.

58. Contrary to Ethicon, Inc. and Johnson & Johnson's representations and marketing to the medical community and to the patients themselves, Ethicon, Inc. and Johnson & Johnson's Gynecare TVT Exact® Continence System has high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused

severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff Connie Hunter, making them defective under the law.

59. The specific nature of the Gynecare TVT Exact® Continence System' defects include, but is not limited to, the following:

a. the use of polypropylene and collagen material in the Gynecare TVT Exact® Continence System and the immune reactions that result from such material, causing adverse reactions and injuries;

b. the design of the Gynecare TVT Exact® Continence System to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Gynecare TVT Exact® Continence System, including, but not limited to, the propensity of the Gynecare TVT Exact® Continence System to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the Gynecare TVT Exact® Continence System, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

e. the propensity of the Gynecare TVT Exact® Continence System for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Gynecare TVT Exact® Continence System, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

g. the propensity of the Gynecare TVT Exact® Continence System for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. the hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i. the propensity of the collagen Gynecare TVT Exact® Continence System to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j. the adverse tissue reactions caused by the collagen Gynecare TVT Exact® Continence System, which are causally related to infection, as the collagen is a foreign organic material from animals;

k. the harshness of cross-linked collagen upon the female pelvic tissue, and the hardening of the Gynecare TVT Exact® Continence System in the body; and

l. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

60. Upon information and belief, Ethicon, Inc. and Johnson & Johnson have consistently underreported and withheld information about the propensity of Ethicon, Inc. and Johnson & Johnson's Gynecare TVT Exact® Continence System to fail and cause injury and complications, and have misrepresented the efficacy and safety of the Gynecare TVT Exact® Continence System, through various means and media, actively and intentionally misleading the FDA, the medical community, patients, and the public at large.

61. Ethicon, Inc. and Johnson & Johnson have further deliberately chosen to forego the conduct of studies and registries to avoid reporting obligations that would be mandated under the federal regulations upon receipt of adverse event information.

62. Despite the chronic underreporting of adverse events associated with the Ethicon, Inc. and Johnson & Johnson's Gynecare TVT Exact® Continence System, the underreporting of events associated with similarly designed competitor products, and Ethicon, Inc. and Johnson & Johnson deliberately avoiding the conduct of studies and registries to avoid the reporting of adverse events, eventually enough complaints were recorded for the FDA to issue a public health notification regarding the dangers of these devices.

63. On October 20, 2008, the Food and Drug Administration ("FDA") issued a Public Health Notification that described over 1,000 complaints (otherwise known as "adverse

events") that had been reported over a three-year period relating to the predicate transvaginal mesh devices, similar to the Gynecare TVT Exact® Continence System. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that the Ethicon, Inc. and Johnson & Johnson are one of the manufacturers of the transvaginal mesh products that are the subject of the notification.

64. On July 13, 2011, the FDA issued a Safety Communication:" UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse." Therein, the FDA advised that it had conducted an updated analysis of adverse events reported to the FDA and complications reported in the scientific literature and concluded that surgical mesh used in transvaginal repair of Pelvic Organ Prolapse was an area of "continuing serious concern." (emphasis added) The FDA concluded that serious complications associated with surgical mesh for transvaginal repair of Pelvic Organ Prolapse, were "not rare." These serious complications include, but are not limited to neuromuscular problems, vaginal scarring/shrinkage and emotional problems. Many of the serious complications required medical and surgical treatment and hospitalization.

65. The FDA concluded in its Safety Communication that it was not clear that transvaginal repair of Pelvic Organ Prolapse with mesh or repair of SUI with mesh kits are more effective than traditional non mesh repair of pelvic organ prolapse. Further, the FDA conducted a systematic review of the published scientific literature from 1996-2011 and concluded that based thereon, that transvaginal pelvic organ prolapse repair with mesh "does not improve symptomatic results or quality of life over traditional non mesh repair." The FDA concluded that "a mesh procedure may put the patient at risk for requiring additional surgery or for the development of new complications. Removal of the mesh due to mesh complications may involve multiple

surgeries and significantly impair the patient's quality of life. Complete removal of mesh may not be possible."

66. The information contained in the FDA's Public Health Notification of October 2008 and the FDA Safety Communication of July 13, 2011, was known or knowable to Ethicon, Inc. and Johnson & Johnson and was not disclosed in oral or written communications, direct to consumer advertising in the form of patient brochures, instructions for use, or labeling.

67. In fact, at the time Ethicon, Inc. and Johnson & Johnson began marketing Gynecare TVT Exact® Continence System, Ethicon, Inc. and Johnson & Johnson were aware that its Gynecare TVT Exact® Continence System was associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011 Safety Communication.

68. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists ("ACOG") and the American Urogynecologic Society ("AUGS") also identified physical and mechanical changes to the mesh inside the body as a serious complication associated with vaginal mesh, stating:

> There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh . . . Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

69. Ethicon, Inc. and Johnson & Johnson knew or should have known about the Gynecare TVT Exact® Continence System's risks and complications identified in the FDA Safety Communication and the ACOG/AUGS Joint Committee Opinion. Ethicon, Inc. and Johnson & Johnson also knew or should have known that: (1) some of the predicate products for the Gynecare TVT Exact® Continence System had high failure and complication rates, resulting in the recall of some of these predicate devices (including a medical device known as Protogen device); (2) that there were and are differences between the Ethicon, Inc. and Johnson & Johnson's Gynecare

TVT Exact® Continence System and some or all of the predicate products, rendering them unsuitable for designation as predicate products; (3) that significant differences exist and existed between the Gynecare TVT Exact® Continence System and their predecessor and predicate products, such that the disclosures to the FDA were and are incomplete and misleading; and (4) that the Gynecare TVT Exact® Continence System was and are causing numerous patients severe injuries and complications.

70. Ethicon, Inc. and Johnson & Johnson suppressed this information and failed to accurately and completely disseminate or share this and other critical information with the FDA, health care providers, and the patients. As a result, the Ethicon, Inc. and Johnson & Johnson actively and intentionally misled, including the medical community, health care providers and patients, into believing that the Gynecare TVT Exact® Continence System and the procedures for implantation were and are safe and effective, leading to the prescription for and implantation of the Gynecare TVT Exact® Continence System into Plaintiff.

71. Ethicon, Inc. and Johnson & Johnson's Gynecare TVT Exact® Continence System is also defective due to Ethicon, Inc. and Johnson & Johnson's failure to adequately warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. the Gynecare TVT Exact® Continence System' propensities to contract, retract, and/or shrink inside the body;

b. the Gynecare TVT Exact® Continence System' propensities for degradation, fragmentation and/or creep;

c. the Gynecare TVT Exact® Continence System' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. the rate and manner of mesh erosion or extrusion;

e. the risk of chronic inflammation resulting from the Gynecare TVT Exact® Continence System;

f. the risk of chronic infections resulting from the Gynecare TVT Exact® Continence System;

g. the risk of permanent vaginal or pelvic scarring as a result of the Gynecare TVT Exact® Continence System;

h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Gynecare TVT Exact® Continence System;

i. the need for corrective or revision surgery to adjust or remove the Gynecare TVT Exact® Continence System;

j. the severity of complications that could arise as a result of implantation of the Gynecare TVT Exact® Continence System;

k. the hazards associated with the Gynecare TVT Exact® Continence System;

l. the Gynecare TVT Exact® Continence System' defects described herein;

m. treatment of pelvic organ prolapse and stress urinary incontinence with the Gynecare TVT Exact® Continence System is no more effective than feasible available alternatives;

n. treatment of pelvic organ prolapse and stress urinary incontinence with the Gynecare TVT Exact® Continence System exposes patients to greater risk than feasible available alternatives;

o. treatment of pelvic organ prolapse and stress urinary incontinence with the Gynecare TVT Exact® Continence System makes future surgical repair more difficult than feasible available alternatives;

p. use of the Gynecare TVT Exact® Continence System puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. removal of the Gynecare TVT Exact® Continence System due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. complete removal of the Gynecare TVT Exact® Continence System may not be possible and may not result in complete resolution of the complications, including pain.

72. Ethicon, Inc. and Johnson & Johnson have underreported information about the propensity of the Gynecare TVT Exact® Continence System to fail and cause injury and complications and have made unfounded representations regarding the efficacy and safety of the Gynecare TVT Exact® Continence System through various means and media, actively and intentionally misleading the FDA, the medical community, patients, and the public at large.

73. Ethicon, Inc. and Johnson & Johnson failed to perform proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Gynecare TVT Exact® Continence System.

74. Ethicon, Inc. and Johnson & Johnson failed to design and establish a safe, effective procedure for removal of the Gynecare TVT Exact® Continence System, or to determine if a safe, effective procedure for removal of the Gynecare TVT Exact® Continence System exists.

75. Feasible and suitable alternatives to the Gynecare TVT Exact® Continence System has existed at all times relevant that do not present the same frequency or severity of risks as do the Gynecare TVT Exact® Continence System.

76. The Gynecare TVT Exact® Continence System was at all times utilized and implanted in a manner foreseeable to Ethicon, Inc. and Johnson & Johnson, as Ethicon, Inc. and Johnson & Johnson generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physicians.

77. Ethicon, Inc. and Johnson & Johnson provided incomplete, insufficient and misleading training and information to physicians regarding the use of the Gynecare TVT Exact® Continence System and the aftercare of patients implanted with the Gynecare TVT Exact® Continence System.

78. The Gynecare TVT Exact® Continence System or Gynecare TVT Exact® Continence System implanted in Plaintiff Connie Hunter was in the same or substantially similar condition as they were when they left Ethicon, Inc. and Johnson & Johnson's possession, and in the condition directed by and expected by Ethicon, Inc. and Johnson & Johnson.

79. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the Gynecare TVT Exact® Continence System include, but are not limited to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, and chronic pelvic pain.

80. In many cases, including Plaintiff Connie Hunter, women have been forced to undergo extensive medical treatment, including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

81. The medical and scientific literature studying the effects of Ethicon, Inc. and Johnson & Johnson's mesh, like that of the Gynecare TVT Exact® Continence System implanted in the relevant Plaintiff, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the Gynecare TVT Exact® Continence System.

82. Ethicon, Inc. and Johnson & Johnson misrepresented to the medical and healthcare community, Plaintiff, the FDA, and the public that the Gynecare TVT Exact® Continence System had been tested and were found to be safe and effective for the purposes of treating incontinence and/or prolapse. These representations were made by Ethicon, Inc. and Johnson & Johnson with

the intent of inducing the medical community, Plaintiff, and the public, to recommend, prescribe, dispense, and purchase the Gynecare TVT Exact® Continence System for use as a means of treatment for stress urinary incontinence and/or prolapse, all of which evinced an indifference to the health, safety, and welfare of Plaintiff.

83. Ethicon, Inc. and Johnson & Johnson failed to undertake their duties to properly know the qualities of their Gynecare TVT Exact® Continence System and in representations to Plaintiff and/or to Plaintiff' healthcare providers, and concealed and intentionally omitted the following material information:

a. That the Gynecare TVT Exact® Continence System was not as safe as other products and procedures available to treat incontinence and/or prolapse;

b. That the Gynecare TVT Exact® Continence System was not as effective as other products and procedures available to treat incontinence and/or prolapsed;

c. That the risk of adverse events with the Gynecare TVT Exact® Continence System was higher than with other products and procedures available to treat incontinence and/or prolapse;

d. That the risk of adverse events with the Gynecare TVT Exact® Continence System was not adequately tested and were known by Ethicon, Inc. and Johnson & Johnson;

e. That the limited clinical testing revealed the Gynecare TVT Exact® Continence System had a higher risk of adverse effects, in addition to, and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

f. That Ethicon, Inc. and Johnson & Johnson failed to follow up on the adverse results from clinical studies and buried and/or misrepresented those findings;

g. That Ethicon, Inc. and Johnson & Johnson were aware of dangers in the Gynecare TVT Exact® Continence System in addition to and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

h. That the Gynecare TVT Exact® Continence System was dangerous and caused adverse side effects, including but not limited to higher incidence of erosion and failure, at a much more significant rate than other products and procedures available to treat incontinence and/or prolapse;

i. That patients needed to be monitored more regularly than usual while using the Gynecare TVT Exact® Continence System and that in the event the Gynecare TVT Exact® Continence System needed to be removed that the procedures to remove them had a very high failure rate and/or needed to be performed repeatedly; Thus:

j. That the Gynecare TVT Exact® Continence System was manufactured negligently;

k. That the Gynecare TVT Exact® Continence System was manufactured defectively; and

l. That the Gynecare TVT Exact® Continence System was designed negligently, and designed defectively.

84. Ethicon, Inc. and Johnson & Johnson were under a duty to disclose to Plaintiff and Plaintiff' physicians, the defective nature of the Gynecare TVT Exact® Continence System, including, but not limited to, the heightened risks of erosion, failure and permanent injury.

85. Ethicon, Inc. and Johnson & Johnson had sole access to material facts concerning the defective nature of the Gynecare TVT Exact® Continence System and their propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used the Gynecare TVT Exact® Continence System.

86. Ethicon, Inc. and Johnson & Johnson's concealment and omissions of material fact concerning the safety of the Gynecare TVT Exact® Continence System were made to cause the Plaintiff, the Plaintiff's physicians and healthcare providers to purchase, prescribe, and/or dispense the Gynecare TVT Exact® Continence System; and/or to mislead Plaintiff and Plaintiff' physicians into reliance and cause Plaintiff to have the Gynecare TVT Exact® Continence System implanted into their bodies.

87. At the time these representations were made by Ethicon, Inc. and Johnson & Johnson, and at the time Plaintiff used the Gynecare TVT Exact® Continence System, Plaintiff was unaware of the falsehood of these representations, and reasonably believed them to be true.

88. Ethicon, Inc. and Johnson & Johnson knew and had reason to know that the Gynecare TVT Exact® Continence System could and would cause severe and grievous personal injury to the users of the Gynecare TVT Exact® Continence System, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

89. In reliance upon these false representations, Plaintiff were induced to, and did use the Gynecare TVT Exact® Continence System, thereby sustaining severe and permanent personal injuries and damages. Ethicon, Inc. and Johnson & Johnson knew or had reason to know that Plaintiff and Plaintiff's physicians and other healthcare providers had no way to determine the truth behind Ethicon, Inc. and Johnson & Johnson's concealment and omissions, and that these included material omissions of facts surrounding the use of the Gynecare TVT Exact® Continence System, as described in detail herein.

90. As a result of Ethicon, Inc. and Johnson & Johnson's research and testing or lack thereof, Ethicon, Inc. and Johnson & Johnson distributed false information, including but not limited to assuring Plaintiff, the public, and Plaintiff's healthcare providers and physicians, that the Gynecare TVT Exact® Continence System was safe for use as a means of providing relief from stress urinary incontinence and/or prolapse and were as safe or safer than other products and/or procedures available and on the market. Further, Ethicon, Inc. and Johnson & Johnson misrepresented to the Plaintiff and to the Plaintiff's physicians that the Gynecare TVT Exact® Continence System was more effective than other means of treatment for these conditions for which they were implanted. As a result of Ethicon, Inc. and Johnson & Johnson's research and testing, or lack thereof, Ethicon, Inc. and Johnson & Johnson intentionally omitted, concealed and

suppressed certain results of testing and research to healthcare professionals, Plaintiff, and the public at large.

91. Ethicon, Inc. and Johnson & Johnson had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public, Plaintiff, Plaintiff' healthcare providers, and the FDA.

92. The information distributed to the public, the medical community, the FDA, and Plaintiff by Ethicon, Inc. and Johnson & Johnson included, but was not limited to, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards and other commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Pelvic Mesh Products.

93. Ethicon, Inc. and Johnson & Johnson intentionally made material misrepresentations to the medical community and public, including Plaintiff, regarding the safety of the Gynecare TVT Exact® Continence System specifically, that the Gynecare TVT Exact® Continence System did not have dangerous and/or serious adverse health safety concerns, and that the Gynecare TVT Exact® Continence System were as safe as other means of treating stress urinary incontinence.

94. Ethicon, Inc. and Johnson & Johnson intentionally failed to inform the public, including Plaintiff, of the high failure rate including erosion, the difficulty of removing the mesh, and the risk of permanent injury.

95. Ethicon, Inc. and Johnson & Johnson chose to over-promote the safety, efficacy and benefits of the Gynecare TVT Exact® Continence System instead.

96. Ethicon, Inc. and Johnson & Johnson's intent and purpose in making these misrepresentations was to deceive the public, the medical community, and Plaintiff; to gain the confidence of the public, the medical community, and Plaintiff; to falsely assure them of the quality and fitness for use of the Gynecare TVT Exact® Continence System; and induce Plaintiff, the public and the medical community to request, recommend, prescribe, dispense, purchase, and continue to use the Gynecare TVT Exact® Continence System.

97. Upon information and belief, Ethicon, Inc. and Johnson & Johnson made claims and representations in its documents submitted to the FDA and its reports to the public and to healthcare professionals and in advertisements that the Gynecare TVT Exact® Continence System did not present serious health risks.

98. These representations, and others made by Ethicon, Inc. and Johnson & Johnson, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

99. These representations, and others made by Ethicon, Inc. and Johnson & Johnson , were made with the intention of deceiving Plaintiff, Plaintiff' healthcare professionals and other members of the healthcare community, and were made in order to induce Plaintiff, and Plaintiff' healthcare professionals, to rely on misrepresentations, and caused Plaintiff to purchase, rely, use, and request the Gynecare TVT Exact® Continence System , and caused her healthcare professionals to dispense, recommend, or prescribe the Gynecare TVT Exact® Continence System.

100. Ethicon, Inc. and Johnson & Johnson recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the Gynecare TVT Exact® Continence System to the public at large, for the purpose of influencing

the sales of Gynecare TVT Exact® Continence System known to be dangerous and defective, and/or not as safe as other alternatives. Ethicon, Inc. and Johnson & Johnson utilized direct-to consumer advertising to market, promote, and advertise the Gynecare TVT Exact® Continence System.

101. At the time the representations were made, Plaintiff and Plaintiff's healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of the Gynecare TVT Exact® Continence System. Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover the false representations of Ethicon, Inc. and Johnson & Johnson, nor would Plaintiff with reasonable diligence have discovered the true facts or Ethicon, Inc. and Johnson & Johnson's misrepresentations.

102. Had Plaintiff known the true facts about the dangers and serious health and/or safety risks of the Gynecare TVT Exact® Continence System, Plaintiff would not have purchased, used, or relied on Ethicon, Inc. and Johnson & Johnson's Gynecare TVT Exact® Continence System .

103. At all times relevant herein, the Gynecare TVT Exact® Continence System was widely advertised and promoted by the Ethicon, Inc. and Johnson & Johnson as a safe and effective treatment for stress urinary incontinence.

104. At all times relevant to this action, Ethicon, Inc. and Johnson & Johnson knew that the Gynecare TVT Exact® Continence System was not safe for the patients for whom they were prescribed and implanted, because the mesh eroded and otherwise malfunctioned, and therefore failed to operate in a safe and continuous manner, causing injuries including, but not limited to, erosion, extrusion, infection, sepsis, chronic foreign body invasion, dense adhesions and worsening dyspareunia. Removal of eroded or infected mesh brings a high rate of life-threatening

complications including permanent disfigurement and hemorrhage. Removal can require multiple surgical interventions in the operating theater for complete removal and results in scarring on fragile compromised pelvic tissue and muscles.

105. Ethicon, Inc. and Johnson & Johnson failed to design and establish a safe, effective procedure for removal of the Gynecare TVT Exact® Continence System, or to determine if a safe, effective procedure for removal of the Gynecare TVT Exact® Continence System exists.

106. At all relevant times herein, Ethicon, Inc. and Johnson & Johnson continued to promote the Gynecare TVT Exact® Continence System as safe and effective even when no clinical trials had been done supporting long- or short-term efficacy.

107. In doing so, Ethicon, Inc. and Johnson & Johnson failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Gynecare TVT Exact® Continence System for treatment of stress urinary incontinence.

108. At all relevant times herein, Ethicon, Inc. and Johnson & Johnson failed to provide sufficient warnings and instructions that would have put Plaintiff Connie Hunter and the general public on notice of the dangers and adverse effects caused by implantation of the Gynecare TVT Exact® Continence System including but not limited to, mesh erosion, dense adhesions, worsening dyspareunia, chronic pain, infection, sepsis, permanent disfigurement and multiple surgeries for mesh removal.

109. The Gynecare TVT Exact® Continence System as designed, manufactured, distributed, sold and/or supplied by Ethicon, Inc. and Johnson & Johnson were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in light of Ethicon, Inc. and Johnson & Johnson's knowledge of lack of safety.

110. As a result of having the Gynecare TVT Exact® Continence System implanted in her, Plaintiff Connie Hunter has experienced significant mental and physical pain and suffering, has sustained injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

111. At all times herein mentioned, the employees, agents, officers and/or directors of the Ethicon, Inc. and Johnson & Johnson named herein participated in, authorized and/or directed the production and promotion of the aforementioned Gynecare TVT Exact® Continence System when they knew of the hazards and dangerous propensities of said Gynecare TVT Exact® Continence System , and thereby actively participated in the tortuous conduct that resulted in the injuries suffered by Plaintiff.

FRAUDULENT CONCEALMENT

112. Ethicon, Inc. and Johnson & Johnson's failure to document or follow up on the known defects in its product, and concealment of known defects, constitutes fraudulent concealment that equitable tolls applicable statutes of limitation.

113. Ethicon, Inc. and Johnson & Johnson are estopped from relying on the statute of limitations defense because Ethicon, Inc. and Johnson & Johnson actively concealed the defects, suppressing reports, failing to follow through on FDA notification requirements, and failing to disclose known defects to physicians. Instead of revealing the defects, Ethicon, Inc. and Johnson & Johnson continued to represent its Gynecare TVT Exact® Continence System as safe for their intended use.

114. Ethicon, Inc. and Johnson & Johnson are and were under a continuing duty to disclose the true character, quality, and nature of risks and dangers associated with their Gynecare TVT Exact® Continence System . Because of Ethicon, Inc. and Johnson & Johnson's concealment

of the true character, quality and nature of their Gynecare TVT Exact® Continence System, Ethicon, Inc. and Johnson & Johnson are estopped from relying on any statute of limitations defense.

115. Ethicon, Inc. and Johnson & Johnson furthered this fraudulent concealment through a continued and systematic failure to disclose information to Plaintiff, physicians and the public.

116. Ethicon, Inc. and Johnson & Johnson's acts before, during and/or after the act causing Plaintiff's injury prevented Plaintiff from discovering the injury or cause thereof.

117. Ethicon, Inc. and Johnson & Johnson's conduct, as described in the preceding paragraphs, amounts to conduct purposely committed, which Ethicon, Inc. and Johnson & Johnson must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of Plaintiff.

118. Ethicon, Inc. and Johnson & Johnson's conduct, as described in the preceding paragraphs, also amounts to a continuing tort, and continues up through and including the date of the filing of Plaintiff's Complaint.

CAUSES OF ACTION:

COUNT I: NEGLIGENCE

119. Plaintiff incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

120. Ethicon, Inc. and Johnson & Johnson had a duty to individuals, including Plaintiff, to use reasonable and ordinary care in designing, manufacturing, marketing, labeling, packaging, and selling the Gynecare TVT Exact® Continence System and recruitment and training of physicians to implant the Gynecare TVT Exact® Continence System.

121. Ethicon, Inc. and Johnson & Johnson were negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging, distributing and selling the Gynecare TVT Exact® Continence System. Ethicon, Inc. and Johnson & Johnson breached their aforementioned duty by:

a. Failing to design the Gynecare TVT Exact® Continence System so as to avoid an unreasonable risk of harm to women in whom the Gynecare TVT Exact® Continence System was implanted, including Plaintiff Connie Hunter.

b. Failing to manufacturer the Gynecare TVT Exact® Continence System so as to avoid an unreasonable risk of harm to women in whom the Gynecare TVT Exact® Continence System was implanted, including Plaintiff Connie Hunter.

c. Failing to use reasonable care in the testing of the Gynecare TVT Exact® Continence System so as to avoid unreasonable risk of harm to women in whom the Gynecare TVT Exact® Continence System was implanted, including Plaintiff Connie Hunter.

d. Failing to use reasonable care in the inspecting the Gynecare TVT Exact® Continence System so as to avoid an unreasonable risk of harm to women in whom the Gynecare TVT Exact® Continence System was implanted, including Plaintiff Connie Hunter.

e. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling Gynecare TVT Exact® Continence System.

122. The reasons that Ethicon, Inc. and Johnson & Johnson's negligence caused the Gynecare TVT Exact® Continence System to be unreasonably dangerous and defective include, but are not limited to:

a. the use of polypropylene and collagen material in the Gynecare TVT Exact® Continence System and the immune reactions that result from such material, causing adverse reactions and injuries;

b. the design of the Gynecare TVT Exact® Continence System to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Gynecare TVT Exact® Continence System, including, but not limited to, the propensity of the Gynecare TVT Exact®

Continence System to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the Gynecare TVT Exact® Continence System, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

e. the propensity of the Gynecare TVT Exact® Continence System for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Gynecare TVT Exact® Continence System, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

g. the propensity of the Gynecare TVT Exact® Continence System for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. the hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i. the propensity of the collagen Gynecare TVT Exact® Continence System to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j. the adverse tissue reactions caused by the collagen Gynecare TVT Exact® Continence System, which are causally related to infection, as the collagen is a foreign organic material from animals;

k. the harshness of cross-linked collagen upon the female pelvic tissue, and the hardening of the Gynecare TVT Exact® Continence System in the body; and

l. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

123. Ethicon, Inc. and Johnson & Johnson also negligently failed to warn or instruct Plaintiff Connie Hunter and/or her health care providers of subjects including, but not limited to, the following:

a. the Gynecare TVT Exact® Continence System' propensities to contract, retract, and/or shrink inside the body;

b. the Gynecare TVT Exact® Continence System' propensities for degradation, fragmentation and/or creep;

c. the Gynecare TVT Exact® Continence System' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. the rate and manner of mesh erosion or extrusion;

e. the risk of chronic inflammation resulting from the Gynecare TVT Exact® Continence System;

f. the risk of chronic infections resulting from the Gynecare TVT Exact® Continence System;

g. the risk of permanent vaginal or pelvic scarring as a result of the Gynecare TVT Exact® Continence System;

h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Gynecare TVT Exact® Continence System;

i. the need for corrective or revision surgery to adjust or remove the Gynecare TVT Exact® Continence System;

j. the severity of complications that could arise as a result of implantation of the Gynecare TVT Exact® Continence System;

k. the hazards associated with the Gynecare TVT Exact® Continence System;

l. the Gynecare TVT Exact® Continence System' defects described herein;

m. treatment of pelvic organ prolapse and stress urinary incontinence with the Gynecare TVT Exact® Continence System is no more effective than feasible available alternatives;

n. treatment of pelvic organ prolapse and stress urinary incontinence with the Gynecare TVT Exact® Continence System exposes patients to greater risk than feasible available alternatives;

o. treatment of pelvic organ prolapse and stress urinary incontinence with the Gynecare TVT Exact® Continence System makes future surgical repair more difficult than feasible available alternatives;

p. use of the Gynecare TVT Exact® Continence System puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. removal of the Gynecare TVT Exact® Continence System due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. complete removal of the Gynecare TVT Exact® Continence System may not be possible and may not result in complete resolution of the complications, including pain.

124. As a direct and proximate result of Ethicon, Inc. and Johnson & Johnson's negligence, Plaintiff Connie Hunter was caused and/or in the future will be caused to suffer severe personal injuries, pain, disability and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

STRICT LIABILITY – DESIGN DEFECT

125. Plaintiff incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

126. The Gynecare TVT Exact® Continence System implanted in Plaintiff was not reasonably safe for its intended use and was defective as described herein with respect to its design. As previously stated, the Gynecare TVT Exact® Continence System's design defects include, but are not limited to:

a. the use of polypropylene and collagen material in the Gynecare TVT Exact® Continence System and the immune reactions that result from such material, causing adverse reactions and injuries;

b. the design of the Gynecare TVT Exact® Continence System to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Gynecare TVT Exact® Continence System, including, but not limited to, the propensity of the Gynecare TVT Exact® Continence System to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the Gynecare TVT Exact® Continence System, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

e. the propensity of the Gynecare TVT Exact® Continence System for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Gynecare TVT Exact® Continence System, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

g. the propensity of the Gynecare TVT Exact® Continence System for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. the hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i. the propensity of the collagen Gynecare TVT Exact® Continence System to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j. the adverse tissue reactions caused by the collagen Gynecare TVT Exact® Continence System, which are causally related to infection, as the collagen is a foreign organic material from animals;

k. the harshness of cross-linked collagen upon the female pelvic tissue, and the hardening of the Gynecare TVT Exact® Continence System in the body; and

l. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

127. As a direct and proximate result of Gynecare TVT Exact® Continence System' defects as described herein, Plaintiff Connie Hunter was caused and/or in the future will be caused to suffer severe personal injuries, pain, disability and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income and other damages.

128. Ethicon, Inc. and Johnson & Johnson are strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective Gynecare TVT Exact® Continence System.

COUNT II: STRICT LIABILITY – MANUFACTURING DEFECT

129. Plaintiff incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

130. The Gynecare TVT Exact® Continence System implanted in Plaintiff Connie Hunter was not reasonably safe for its intended use and was defective as described herein as a matter of law with respect to its manufacture, in that it deviated materially from Ethicon, Inc. and Johnson & Johnson ' design and manufacturing specifications in such a manner as to pose unreasonable risks of serious bodily harm to said Plaintiff.

131. As a direct and proximate result of the Gynecare TVT Exact® Continence System' aforementioned defects, Plaintiff Connie Hunter was caused and/or in the future will be caused to suffer severe personal injuries, pain, disability, suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

132. Ethicon, Inc. and Johnson & Johnson are strictly liable to Plaintiff for designing, manufacturing,

marketing, labeling, packaging and selling a defective Gynecare TVT Exact® Continence System.

COUNT III: STRICT LIABILITY – FAILURE TO WARN

133. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

134. Gynecare TVT Exact® Continence System was defective by reason of failure of Ethicon, Inc. and Johnson & Johnson to provide adequate warnings or instructions.

135. Ethicon, Inc. and Johnson & Johnson failed to properly and adequately warn and instruct Plaintiff and her healthcare providers as to the proper candidates, if any, and the safest and most effective methods of implantation and use of Gynecare TVT Exact® Continence System.

136. Ethicon, Inc. and Johnson & Johnson failed to properly and adequately warn and instruct Plaintiff and her healthcare providers as to the risks and benefits of Gynecare TVT Exact® Continence System, given the Plaintiff's condition and need for information.

137. Ethicon, Inc. and Johnson & Johnson failed to properly and adequately warn and instruct Plaintiff and her healthcare providers with regard to the inadequate research and testing of the Gynecare TVT Exact® Continence System, and the complete lack of a safe, effective procedure for removal of the Gynecare TVT Exact® Continence System.

138. Ethicon, Inc. and Johnson & Johnson failed to provide such adequate warning or instruction that a manufacturer exercising reasonable care would have provided to physicians who implanted the Gynecare TVT Exact® Continence System or to those women who had been implanted with the Gynecare TVT Exact® Continence System concerning the following risks, given their condition and need for information. Ethicon, Inc. and Johnson & Johnson had actual or constructive knowledge of the following risks at the time the Gynecare TVT Exact® Continence System left Ethicon, Inc. and Johnson & Johnson's control and were being marketed:

a. The high failure rate of the Gynecare TVT Exact® Continence System;

b. The high rate of infections and abscesses caused by the Gynecare TVT Exact® Continence System;

c. The high rate of vaginal erosions and extrusions caused by the Gynecare TVT Exact® Continence System;

d. The high rate of chronic pain caused by the Gynecare TVT Exact® Continence System;

e. The necessity to remove the Gynecare TVT Exact® Continence System from the patient's body in the event of Gynecare TVT Exact® Continence System failure, infections, abscesses, erosion, extrusion or other complication; and

f. The difficulty in removing the Gynecare TVT Exact® Continence System Gynecare TVT Exact® Continence System from the patient's body, including the complete lack of a safe, effective procedure for removal of the Gynecare TVT Exact® Continence System.

139. After receiving notice of numerous bodily injuries resulting from the Gynecare TVT Exact® Continence System Ethicon, Inc. and Johnson & Johnson failed to provide such post-marketing or post-sale warnings or instructions that a manufacturer exercising reasonable care should have provided to physicians who implanted the Gynecare TVT Exact® Continence System or those women who had been implanted with the Gynecare TVT Exact® Continence System that the Gynecare TVT Exact® Continence System were causing an unreasonably high rate of complications such as mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistulae, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathy, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, and prolapse of organs. Furthermore Ethicon, Inc. and Johnson & Johnson failed to provide post-marketing or post-sale warning instructions concerning the necessity to remove the Pelvic Mesh Gynecare TVT Exact® Continence System from the patient's body in the event of the Gynecare TVT Exact® Continence System failure or other complications.

140. Ethicon, Inc. and Johnson & Johnson intentionally, recklessly, and maliciously misrepresented the safety, risks and benefits of the Gynecare TVT Exact® Continence System,

understating the risks and exaggerating the benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of Plaintiff.

141. Absence of a warning or instruction renders the Gynecare TVT Exact® Continence System unreasonably dangerous for its intended use.

142. As a direct and proximate result of Ethicon, Inc. and Johnson & Johnson's wrongful conduct, including Ethicon, Inc. and Johnson & Johnson's wrongful design, manufacture, marketing, sale and distribution of the Gynecare TVT Exact® Continence System, both at the time of marketing and after the sale of the Gynecare TVT Exact® Continence System, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

143. Ethicon, Inc. and Johnson & Johnson are strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling defective product.

COUNT IV: NEGLIGENT AND/OR INTENTIONAL MISREPRESENTATION

144. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

145. Ethicon, Inc. and Johnson & Johnson had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that the Gynecare TVT Exact® Continence System had not been adequately tested and found to be safe and effective for the treatment of incontinence and prolapse. The representations made by Ethicon, Inc. and Johnson & Johnson, in fact, were false.

146. Ethicon, Inc. and Johnson & Johnson failed to exercise ordinary care in the representations concerning the Gynecare TVT Exact® Continence System while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in

interstate commerce, because Ethicon, Inc. and Johnson & Johnson negligently misrepresented the Gynecare TVT Exact® Continence System's high risk of unreasonable, dangerous, adverse side effects

147. Ethicon, Inc. and Johnson & Johnson breached their duty in representing that the Gynecare TVT Exact® Continence System had no serious side effects different from older generations of similar products and/or procedures to Plaintiff, Plaintiff's physicians, and the medical and healthcare community.

148. As a foreseeable, direct and proximate result of the negligent misrepresentation of Ethicon, Inc. and Johnson & Johnson as set forth herein, Ethicon, Inc. and Johnson & Johnson knew, and had reason to know, that the Gynecare TVT Exact® Continence System had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that it created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including, erosion, pain and suffering, surgery to remove the Gynecare TVT Exact® Continence System, and other severe and personal injuries, which are permanent and lasting in nature

149. As a direct and proximate result of Ethicon, Inc. and Johnson & Johnson's negligent and/or intentional misrepresentation, Plaintiff Connie Hunter was caused and/or in the future will be caused to suffer severe personal injuries, pain, disability, suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

COUNT V: FRAUDULENT CONCEALMENT

150. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

152. Throughout the relevant time period, Ethicon, Inc. and Johnson & Johnson knew that their Pelvic Mesh Products were defective and unreasonably unsafe for their intended purpose.

153. Ethicon, Inc. and Johnson & Johnson fraudulently concealed from and/or failed to disclose to or warn Plaintiff, their physicians and the medical community that their Gynecare TVT Exact® Continence System were defective, unsafe, and unfit for the purposes intended, and that they were not of merchantable quality.

154. Ethicon, Inc. and Johnson & Johnson were under a duty to Plaintiff to disclose and warn of the defective nature of the Products because:

a. Ethicon, Inc. and Johnson & Johnson were in a superior position to know the true quality, safety and efficacy of the Ethicon, Inc. and Johnson & Johnson 's Gynecare TVT Exact® Continence System;

b. Ethicon, Inc. and Johnson & Johnson knowingly made false claims about the safety and quality of the Ethicon, Inc. and Johnson & Johnson's Gynecare TVT Exact® Continence System in the documents and marketing materials Ethicon, Inc. and Johnson & Johnson provided to the FDA, physicians, and the general public; and

c. Ethicon, Inc. and Johnson & Johnson fraudulently and affirmatively concealed the defective nature of the Ethicon, Inc. and Johnson & Johnson's Gynecare TVT Exact® Continence System from Plaintiff.

155. The facts concealed and/or not disclosed by Ethicon, Inc. and Johnson & Johnson to Plaintiff were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use the Ethicon, Inc. and Johnson & Johnson's Gynecare TVT Exact® Continence System.

156. Ethicon, Inc. and Johnson & Johnson intentionally concealed and/or failed to disclose the true defective nature of the Products so that Plaintiff would request and purchase the Ethicon, Inc. and Johnson & Johnson's Gynecare TVT Exact® Continence System, and that her healthcare providers would dispense, prescribe, and recommend the Ethicon, Inc. and Johnson & Johnson's Gynecare TVT Exact® Continence System , and Plaintiff justifiably acted or relied

upon, to her detriment, the concealed and/or non-disclosed facts as evidenced by her purchase of the Ethicon, Inc. and Johnson & Johnson's Gynecare TVT Exact® Continence System.

157. Ethicon, Inc. and Johnson & Johnson, by concealment or other action, intentionally prevented Plaintiff and Plaintiff's physicians and other healthcare providers from acquiring material information regarding the lack of safety and effectiveness of the Ethicon, Inc. and Johnson & Johnson's transvaginal mesh products, and are subject to the same liability to Plaintiff for Plaintiff' pecuniary losses, as though Ethicon, Inc. and Johnson & Johnson had stated the non-existence of such material information regarding the Ethicon, Inc. and Johnson & Johnson ' Gynecare TVT Exact® Continence System's lack of safety and effectiveness and dangers and defects, and as though Ethicon, Inc. and Johnson & Johnson had affirmatively stated the non-existence of such matters that Plaintiff were thus prevented from discovering the truth. Ethicon, Inc. and Johnson & Johnson therefore have liability for fraudulent concealment under all applicable law, including, *inter alia*, *Restatement (Second) of Torts* § 550 (1977).

158. As a proximate result of the Ethicon, Inc. and Johnson & Johnson's conduct, Plaintiff have been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

COUNT VI: BREACH OF EXPRESS WARRANTY

159. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

160. At all relevant and material times, Ethicon, Inc. and Johnson & Johnson manufactured, distributed, advertised, promoted, and sold the Ethicon, Inc. and Johnson & Johnson's Gynecare TVT Exact® Continence System.

161. Ethicon, Inc. and Johnson & Johnson made assurances to the general public, hospitals and health care professionals that the Gynecare TVT Exact® Continence System was safe and reasonably fit for its intended purpose.

162. Plaintiff Connie Hunter and/or her health care provider chose the Gynecare TVT Exact® Continence System based upon Ethicon, Inc. and Johnson & Johnson's respective warranties and representations regarding the safety and fitness of the Gynecare TVT Exact® Continence System.

163. Plaintiff Connie Hunter, individually and/or by and through her physician, reasonably relied upon Ethicon, Inc. and Johnson & Johnson's respective express warranties and guarantees that the Gynecare TVT Exact® Continence System was safe, merchantable and reasonably fit for their intended purposes.

164. Ethicon, Inc. and Johnson & Johnson breached these express warranties because the Gynecare TVT Exact® Continence System implanted in Plaintiff were unreasonably dangerous and defective and not as Ethicon, Inc. and Johnson & Johnson represented.

165. As a direct and proximate result of Defendant's breaches of the aforementioned express warranties, Plaintiff Connie Hunter was caused and/or in the future will be caused to suffer severe personal injuries, pain, disability, suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

COUNT VII: BREACH OF IMPLIED WARRANTY

166. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

167. Ethicon, Inc. and Johnson & Johnson impliedly warranted that the Gynecare TVT Exact® Continence System was merchantable and was fit for the ordinary purpose for which it was intended.

168. When the Gynecare TVT Exact® Continence System was implanted in Plaintiff Connie Hunter to treat her for Stress Urinary Incontinence and other symptoms, it was being used for the ordinary purposes for which it was intended.

169. Plaintiff Connie Hunter, individually and/or by and through her physician, relied upon Ethicon, Inc.'s and Johnson & Johnson's implied warranties of merchantability in consenting to have the Gynecare TVT Exact® Continence System implanted in her.

170. Ethicon, Inc. and Johnson & Johnson breached these implied warranties of merchantability because the Gynecare TVT Exact® Continence System implanted in the Plaintiff was neither merchantable nor suited for its intended use as warranted.

171. Ethicon, Inc. and Johnson & Johnson's breaches of their implied warranties resulted in the implantation of an unreasonably dangerous and defective Gynecare TVT Exact® Continence System in Plaintiff's body, placing Plaintiff's health and safety in jeopardy.

172. As a direct and proximate result of Ethicon, Inc. and Johnson & Johnson's breaches of the aforementioned implied warranties, Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain, disability, suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

COUNT VIII: UNJUST ENRICHMENT

173. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

174. Plaintiff paid for the Gynecare TVT Exact® Continence System for the purpose of treatment of stress urinary incontinence and/ or pelvic organ prolapse or other similar conditions.

175. Ethicon, Inc. and Johnson & Johnson have accepted payment by Plaintiff and others on Plaintiff's behalf for the purchase of the Gynecare TVT Exact® Continence System.

176. Plaintiff has not received the safe and effective medical devices for which they paid.

177. It would be inequitable for Ethicon, Inc. and Johnson & Johnson to keep this money since Plaintiff did not in fact receive a safe and effective medical device as represented by Ethicon, Inc. and Johnson & Johnson.

COUNT IX: PUNITIVE DAMAGES

178. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

179. Ethicon, Inc. and Johnson & Johnson knew or should have known that the Gynecare TVT Exact® Continence System was defective and presented unreasonable risks of harm to Plaintiff Connie Hunter.

180. Ethicon, Inc. and Johnson & Johnson sold the Gynecare TVT Exact® Continence System to Plaintiff's health care providers and other providers in Missouri and throughout the United States without doing adequate testing to ensure that the Gynecare TVT Exact® Continence System was reasonably safe for implantation in the female pelvic area.

181. Ethicon, Inc. and Johnson & Johnson sold the Gynecare TVT Exact® Continence System to Plaintiff's health care providers and other health care providers in Missouri and throughout the United States without doing adequate testing to determine whether the Gynecare TVT Exact® Continence System degraded *in vivo.* The Gynecare TVT Exact® Continence

System does, in fact, degrade *in vivo*, which causes the severe and debilitating injuries suffered by Plaintiff Connie Hunter and numerous other women.

182. Ethicon, Inc. and Johnson & Johnson ignored reports from health care providers throughout the United States of the Gynecare TVT Exact® Continence System's failures to perform as intended, which led to the severe and debilitating injuries suffered by Plaintiff Connie Hunter and numerous other women. Rather than doing adequate testing to rule out the Gynecare TVT Exact® Continence System's design flaws or the processes by which the Gynecare TVT Exact® Continence System is manufactured as the cause of these severe and debilitating injuries, Ethicon, Inc. and Johnson & Johnson chose instead to instruct its sales forces to downplay the Gynecare TVT Exact® Continence System's risks, and continued to market and sell the Gynecare TVT Exact® Continence System as safe and effective treatments of Stress Urinary Incontinence.

183. The wrongs done by Ethicon, Inc. and Johnson & Johnson were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff for which the law would allow, and for which Plaintiff will seek at the appropriate time under governing law, the imposition of exemplary damages, in that Ethicon, Inc. and Johnson & Johnson's conduct, including the failure to comply with the applicable federal standards, was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Ethicon, Inc. and Johnson & Johnson's standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Ethicon, Inc. and Johnson & Johnson were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifferences to the rights, safety, or welfare of others; or included a material representation that was false, with Ethicon, Inc. and Johnson & Johnson

knowing that it was false or with reckless disregard as to its truth and as a perspective assertion, with the intent that the representation would be acted on by Plaintiff.

184. Plaintiff therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

COUNT X: MISSOURI MERCHANDISING PRACTICES ACT

185. Plaintiff Connie Hunter incorporates herein by reference the foregoing allegations of this Petition as if fully set forth herein and further allege as follows:

186. Plaintiff brings this action as a consumer pursuant to R.S.Mo. §407.020 and 15 CSR60-8.020.

187. Ethicon, Inc. and Johnson & Johnson were at all times relevant hereto lawfully doing business in the State of Missouri and this claim arose in St. Louis, State of Missouri.

188. At all times relevant, Ethicon, Inc. and Johnson & Johnson sold and advertised for sale merchandise or services in trade or commerce, specifically their transvaginal mesh device.

189. During and before the time of the transaction referred to above, Ethicon, Inc. and Johnson & Johnson engaged in unlawful practices as defined in R.S.Mo. §407.020 by misrepresenting the efficacy of their product to physicians and hospitals and by failing to warn of known defects in shape, composition, weight, physical, chemical and mechanical properties and are inappropriately engineered for use in the human body, which can cause debilitating injury and illness.

190. As a direct and proximate result of the aforementioned unfair practices and concealment, omission and suppression of material facts from Plaintiff's physicians and other health care providers, Plaintiff endured pain and suffering, disability or physical impairment,

mental anguish, inconvenience, loss of capacity for the enjoyment of life experienced in the past or to be experienced in the future, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future.

191. Plaintiff Connie Hunter was directly and proximately harmed by the aforesaid violation of the Missouri Merchandising Practices Act by Ethicon, Inc. and Johnson & Johnson as described above, and she has suffered and will continue to suffer injuries, including but not limited to pain and suffering, disability or physical impairment, mental anguish, inconvenience, loss of capacity for the enjoyment of life experienced in the past or to be experienced in the future, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future

192. Plaintiff has incurred and will incur attorney fees in prosecuting this action for which Ethicon, Inc. and Johnson & Johnson are liable under R.S.Mo. §407.020.

193. The conduct of Ethicon, Inc. and Johnson & Johnson as described above demonstrated willful, wanton and malicious conduct, as well as a complete indifference to or conscious disregard for the safety of Plaintiff and others, thereby justifying an award of punitive damages in such sum which will serve to punish Ethicon, Inc. and Johnson & Johnson and to deter Ethicon, Inc. and Johnson & Johnson and others from like conduct in the future.

194. WHEREFORE, Plaintiff demand judgment in their favor and against Ethicon, Inc. and Johnson & Johnson in a sum in excess of $75,000; for costs herein incurred; for attorney's fees; and for such other and further relief as this Court deems just and proper.

PRAYER FOR RELIEF

195. WHEREFORE, Plaintiff demands judgment against Ethicon, Inc. and Johnson & Johnson, and each of them, individually, jointly and severally and request compensatory damages,

together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

i. Compensatory damages in excess of the minimum jurisdictional amount, including, but not limited to, compensation for injury, pain, suffering, mental anguish, emotional distress, loss of enjoyment of life, loss of consortium, and other non-economic damages in an amount to be determined by the trier of fact in this action:

ii. Economic damages in the form of medical expenses, out-of-pocket expenses, life care expenses, and other economic damages in an amount to be determined by the trier of fact in this action;

iii. Attorney's fees, expenses, and other costs of this action;

iv. Punitive damages; and

v. Such relief as this Honorable Court deems necessary, just and proper.

PLAINTIFF DEMANDS A TRIAL BY JURY

Dated: June 5, 2019

Respectfully submitted,

/s/ Eric D. Holland
Eric D. Holland – Attorney Bar #: 39935
HOLLAND LAW FIRM
300 N. Tucker Blvd., #801
St. Louis, MO 63101
Telephone: (314)241-8111
Fax: (314)241-5554
eholland@hollandtrial lawyers.com

/s/ Bert Tarrant Dunken, Jr
Bert Tarrant Dunken, Jr.
TX State Bar No. 06231400
S.D. Tex ID No. 152012
DUNKEN LAW GROUP
1 Sugar Creek Center Blvd, Suite 1075
Sugar Land, TX 77478
Telephone: (713) 554-6780
Facsimile: (281) 783-6249
tdunken@dunkenlaw.com

Pro Hace Vice to be filed